

JAN 27 1997

K963929

510(k) Summary
of Safety and Effectiveness

This submission covers the upgrade of the Jobst Athrombic Pump System 2000 to the System 2100. It also covers the use of thigh length sleeves with the System 2100. This device is classified as a compressible limb sleeve under 21 CFR 870.5800.

The System 2100 with the thigh length sleeve is substantially equivalent to the Flowtron DVT/thigh sleeve system marketed by Huntleigh Healthcare in the mode of operation and the indications for use. Both products are used to help prevent deep vein thrombosis and pulmonary embolism in recumbent patients by increasing deep venous blood flow return from the lower extremities. This is accomplished by intermittent compression of the muscles in the calf and thigh.

Furthermore, the Jobst Athrombic Pump console for the System 2100 is almost identical to the pump console for the System 2000 previously cleared, except for a few minor modifications that are clearly identified in this submission.

The Jobst Athrombic Pump System 2000 with calf sleeve and the Flowtron DVT/thigh sleeve systems have both proven effective for several years. The System 2100 combines the benefits of the two systems and provides a device that is safe and effective.

Date: August 16, 1996

Prepared by: Angelo R. Pereira
Beiersdorf-Jobst, Inc.
5825 Carnegie Boulevard
Charlotte, NC 28209
Phone: (704) 551-7178